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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,413	09/10/2003	Peter Kite	13317.1001cip	4621

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EXAMINER	
KANTAMNENI, SHOBHA	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,413	KITE ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32,34,37,39,41,42,44-47 and 55-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *32, 34, 37, 39, 41-42, 44-47, 55-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/05/2005 has been entered.

Claims 32, 34, 37, 39, 41-42, 44-47, and 55-57 are pending.

The Amendment received July 05, 2005, amended claims 32, 34, 37, 39, 41, 42, 44-47, 55-56, and added new claim 57. The Amendment also cancelled claims 40 and 54.

Applicant's amendment to claims 32, and 56 by inserting new limitation "packed in a sterile, pyrogen-free form", and cancellation of claims 40, and 54 overcomes the rejection of claims 32, 37, 40, 45, 54, 56 only under 35 U.S.C. 102(b) as being anticipated by Kurginski (GB 1 279 148).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Applicant's amendment by eliminating the word "safe" in claims 32 and 56, and by eliminating the word "modest" in claim 32, and cancellation of claim 40 is sufficient to

overcome the rejection of claims 32, 34, 37, 39, 40-42, 44-47, and 56 under 35 U.S.C. 112, second paragraph, as being vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 55, 34, 41, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Fahim (WO 00/13656, PTO-892).

Fahim discloses antimicrobial compositions comprising about 0.025 to about 8.0 % by weight of a salt of EDTA such as tetra sodium EDTA, and the composition has a pH from about 5.0 to about 11.0. See page 10, lines 10-25; and page 11, lines 6-10. It is taught that the viscosity of the composition can be adjusted by adding sodium chloride. See page lines 15-16. The antimicrobial properties of the compositions were also reported. It is further taught that by increasing the EDTA-Na4 concentration from 2 to 3.0 % by weight provided a substantial increase in bacteria reduction. See page 23, Table 8, prototype 10, wherein the composition comprises 3 % by weight of tetra sodium EDTA, NaCl, water and a pH of 9.5. The antimicrobial compositions comprising tetra-sodium EDTA taught by Fahim are used for cleaning skin. See page 41, claims 35-37.

While the references does not explicitly state that "composition has an osmolarity of from 240-500 mOsM/Kg", as in claim 55, since Fahim discloses the same tetrasodium EDTA as that recited in the instant invention, the composition should possess claimed properties. A compound and its properties are inseparable (*IN re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963), thus, since Fahim discloses the same tetrasodium EDTA as that recited in the instant invention, the composition should possess claimed properties.

Thus Fahim anticipates instant claim 55, 34, 41, 42.

Claim 55, 34, 41, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurginski (GB 1 279 148, PTO-892 of record).

Kurginski teaches a composition comprising a chelating agent such as alkali metal salts or partial salts of ethylenediaminetetraacetic acid (EDTA) in an amount of 0.25 to 15 parts by weight i.e 0.25-15 %, a loweralkanol of 1 to 4 carbon atoms in the amount of 1 to 5 parts i.e less than 10 %, (such as methanol, ethanol etc), an alkanolamine in an amount of 0.8 to 6 parts, a mixture of two or more different loweralkyl ether alcohols in an amount of 1 to 5 parts, and the rest is water in an amount to complete said composition, for cleaning soils that accumulate in toilets and sanitary facilities due to bacterial and fungal growth by applying to the surface a said composition. See page 1, lines 12-15, lines 61-64. The PH of the composition is from 7 to 12. See page 2, lines 17-22, lines 48-52, lines 59-60; page 4, claims 1, 4, 5. See

EXAMPLE 1, page 4, wherein tetrasodium salt of ethylenediaminetetraacetic acid is used, and the pH is 10.2.

While the references does not explicitly state that "composition has an osmolarity of from 240-500 mOsM/Kg", as in claim 55, since Kurginski discloses the same tetrasodium EDTA as that recited in the instant invention, the composition should possess claimed properties.

While the references does not explicitly state that "composition has a bactericidal effect over a broad spectrum of microbes", as in claim 55, the Examiner respectfully points out that a compound and its properties are inseparable (*IN re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). Thus, since Kurginski teaches the same tertasodium EDTA as that recited in the instant invention, the composition should possess the bactericidal effect over a broad range of microbes.

Thus Kurginski anticipates instant claims 34, 41, 42, and 55.

35 USC § 103 Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32, 39, 44, 45, and 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656) as applied to claim 34, 41, 42, and 55 above, in view of Wilder (US 6,500,861, PTO-892).

Fahim discloses antimicrobial compositions comprising about 0.025 to about 8.0 % by weight of a salt of EDTA such as tetra sodium EDTA, and the composition has a pH from about 5.0 to about 11.0. See page 10, lines 10-25; and page 11, lines 6-10. It taught that the viscosity of the composition can be adjusted by adding sodium chloride. See page lines 15-16. The antimicrobial properties of the compositions were also reported. It is further taught that by increasing the EDTA-Na4 concentration from 2 to 3.0 % by weight provided a substantial increase in bacteria reduction. See page 23, Table 8, prototype 10, wherein the composition comprises 3 % by weight of tetra sodium EDTA, NaCl, water and a pH of 9.5. The antimicrobial compositions comprising tetra-sodium EDTA taught by Fahim are used for topical application such as for cleaning skin. See page 41, claims 35-37.

Fahim does not specifically teach that the composition is packaged in a sterile, pyrogen free form.

Wider teaches antimicrobial compositions for eliminating infections from various surfaces and materials, including the surface of the body. .It is also taught that the antimicrobial compositions can be administered as a liquid either orally or through a suitable delivery system, such as a catheter. See column 1, lines 8-20; column 2, lines 30-34; and column 4, lines 10-14. It is further taught that the antimicrobial compositions are packaged in a sterile and pyrogen free form, and can be introduced into the abdominal cavity through a catheter. See column 6, lines 9-10; column 7, lines 51-55.

It would have been obvious to a person of ordinary skill in the art to employ the antimicrobial composition of Fahim in a sterile pyrogen free condition because Wider teaches antimicrobial compositions as packaged in a sterile and pyrogen free form.

One of ordinary skill in the art at the time of invention would have been motivated to employ the claimed antiseptic compositions in a sterile pyrogen free form as conventional with antimicrobial compositions with the expectation of using the composition in catheters.

In claim 56, the intended use of a product or composition "wherein the lock flush composition is biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes", do not further limit the claim because the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656), in view of Wider (US 6,500,861 B1), as applied to Claims 32, 39, 44, 45, and 56-57 above, and further in view of Root et al. (Antimicrobial Agents and Chemotherapy. Nov. 1988, pages 1627-1631, PTO-892).

Fahim , and Wider are as discussed above.

Fahim does not specifically teach the antimicrobial composition in a single-dosage vial.

Root et al. teaches a method for disinfecting a catheter by contacting (flushing) with an antimicrobial composition of aqueous EDTA solution having a concentration of 20 mg/ml. The EDTA used by Root et al. is in the form of the disodium salt. Root also teaches that the EDTA is used as a topical antiseptic in gram-negative infections. See page 1627, paragraphs 3, and 6. Root further teaches a sterile polystyrene test tubes (vials) containing the antimicrobial composition of disodium EDTA at a concentration of 20 mg/ml (2 %). See page 1628, lines 18-21.

It would have been obvious to a person of ordinary skill in the art to employ the antimicrobial composition of Fahim in a sterile condition in a single-dosage vial from the teachings of Root et al.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fahim (WO 00/13656, PTO-892), in view of Wilder (US 6,500,861, PTO-892), as applied to Claims 32, 39, 44, 45, and 56-57 above, and further in view Remington's Pharmaceutical Sciences.

Fahim fails to recite the employment of the composition in a prefilled syringe.

Remington's Pharmaceutical Sciences teaches sterile, pyrogen free solutions of sodium chloride as ideal for injection. It also discloses that hypodermic syringes are used for injection of liquids. See page 1837. Remington also warns against injection of

solutions containing pyrogens (See page 835, column 2, paragraph 1), and to maintain conventional sterile methodology for injected medicaments.

Possessing this teaching by Remington Pharmaceutical Sciences the skilled artisan would have been motivated to provide a syringe filled with an EDTA solution with the expectation of using such sterile, pyrogen free solution for injection.

Claims 32, 37, 44, 45, 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurginski (GB 1 279 148, PTO-892 of record) as applied to claims 55, 34, 41, 42 above, in view of Fahim (WO 00/13656), and in view of Wilder (US 6,500,861 B1).

Kurginski is as discussed above.

Kurginski does not specifically teach that the composition is packaged in a sterile, pyrogen free form.

Fahim discloses antimicrobial compositions comprising about 0.025 to about 8.0 % by weight of a salt of EDTA such as tetra sodium EDTA, and the composition has a pH from about 5.0 to about 11.0. See page 10, lines 10-25; and page 11, lines 6-10.

Wilder teaches antimicrobial compositions for eliminating infections from various surfaces and materials including the surface of the body. .It is also taught that the antimicrobial compositions can be administered as a liquid either orally or through a suitable delivery system, such as a catheter. See column 1, lines 8-20; column 2, lines 30-34; and column 4, lines 10-14. It is further taught that the antimicrobial compositions

are packaged in a sterile and pyrogen free form, and can be introduced into the abdominal cavity through a catheter. See column 6, lines 9-10; column 7, lines 51-55.

It would have been obvious to a person of ordinary skill in the art to employ the compositions comprising tetra-sodium salt of EDTA as antimicrobial composition, as Fahim teaches that the compositions comprising tetra-sodium EDTA can be used as antimicrobial compositions.

It would have been obvious to a person of ordinary skill in the art to employ the antimicrobial composition of Fahim in a sterile pyrogen free condition because Wider teaches antimicrobial compositions as packaged in a sterile and pyrogen free form.

Thus from the teachings of Fahim, and Wilder, one of ordinary skill in the art at the time of invention would have been motivated to employ the claimed antiseptic compositions in a sterile pyrogen free form as conventional with antimicrobial compositions with the expectation of using the composition in catheters.

Response to Arguments

Claim Rejection- 35 U.S.C. 102(b):

Applicant argues that "Although water is the highest percentage constituent in the liquid composition, applicants perceive no teaching or suggestion in kurginski of a composition comprising a different solvent admixture or fewer solvent components or of a composition in which the solution is water." This argument is not persuasive because Kurginski discloses the composition comprising tetra-sodium EDTA, as a solution in water and thus reads on the instant claims which are directed to a composition

comprising tetra-sodium EDTA as a solution in water. Note that the instant claims does not exclude other solvent components.in the composition.

Claim Rejection- 35 U.S.C. 103(a):

Applicant argues that "solubilizing gelatinous microorganisms is quite distinct from producing a bactericidal effect and it is clear that Kurginski does not teach that its compositions have a bactericidal effect." This argument is not persuasive because it is not commensurate in scope with the instant claims. Instant claims are directed to a "composition comprising at least one salt of ethylene diamine tetraacetic acid (EDTA) in solution at a concentration of at least 2.0 % (WV) and a pH of at least 9.5." The prior art art teaches the composition comprising a chelating agent such as alkali metal salts or partial salts of ethylenediaminetetraacetic acid (EDTA) in an amount of 0.25 to 15 parts by weight i.e 0.25-15 % in water , wherein the composition has a pH of between 7 to 12. See page 2, lines 17-22, lines 48-52, lines 59-60; page 4, claims 1, 4, 5. See EXAMPLE 1, page 4, wherein tetrasodium salt of ethylenediaminetetraacetic acid is used. Thus the prior art teaches applicant's composition and thus should possess the bactericidal effect over a broad spectrum of microbes.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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